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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/076,115	05/12/1998	CHRISTIAN E. GRUBER	0942.4350001	4470	
26111 7	26111 7590 10/06/2003			EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W.			TUNG, JOYCE		
	N, DC 20005		ART UNIT	PAPER NUMBER	
	,		1637	41	
			DATE MAILED: 10/06/2003	3	

Please find below and/or attached an Office communication concerning this application or proceeding.



Application No. 09/076,115

Applicant(s)

Gruber et al

Examiner

Office Action Summary

Joyce Tung

Art Unit **1637**



	The MAILING DATE of this communication appears of	on the cover sheet with the correspondence address			
	for Reply OPTENED STATUTORY BEDIOD FOR BEDIVIS SET	TO EVOIDE 2 MONTH(S) EDOM			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.					
	ions of time may be available under the provisions of 37 CFR 1.136 (a). In r	no event, however, may a reply be timely filed after SIX (6) MONTHS from the			
- If the p	y date of this communication. period for reply specified above is less than thirty (30) days, a reply within the period for reply is specified above, the maximum statutory period will apply ar				
- Failure	to reply within the set or extended period for reply will, by statute, cause the	e application to become ABANDONED (35 U.S.C. § 133).			
•	ply received by the Office later than three months after the mailing date of the patent term adjustment. See 37 CFR 1.704(b).	ns communication, even if timely filed, may reduce any .			
Status					
1) <u>X</u>	Responsive to communication(s) filed on Jun 6, 200	03			
2a) 🗌	This action is FINAL . 2b) 💢 This action	on is non-final.			
3) 🗆	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
Disposi	tion of Claims				
4) 💢	Claim(s) <u>64-122</u>	is/are pending in the application.			
4	la) Of the above, claim(s)	is/are withdrawn from consideration.			
5) 🗆	Claim(s)	is/are allowed.			
6) 💢	Claim(s) <u>64-122</u>	is/are rejected.			
7) 🗆	Claim(s)	is/are objected to.			
8) 🗆	Claims	are subject to restriction and/or election requirement.			
Applica	ition Papers				
9) 🗆	The specification is objected to by the Examiner.				
10)	The drawing(s) filed on is/are	a) accepted or b) objected to by the Examiner.			
	Applicant may not request that any objection to the di	rawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11)					
	If approved, corrected drawings are required in reply t	o this Office action.			
12)	The oath or declaration is objected to by the Examin	ner.			
Priority	under 35 U.S.C. §§ 119 and 120				
13)□	Acknowledgement is made of a claim for foreign pr	iority under 35 U.S.C. § 119(a)-(d) or (f).			
a) [☐ All b) ☐ Some* c) ☐ None of:				
	1. \square Certified copies of the priority documents have	e been received.			
	2. \square Certified copies of the priority documents have	e been received in Application No			
	3. Copies of the certified copies of the priority do application from the International Burea	au (PCT Rule 17.2(a)).			
_	ee the attached detailed Office action for a list of the				
-	Acknowledgement is made of a claim for domestic				
. —	☐ The translation of the foreign language provisional				
15)∐	Acknowledgement is made of a claim for domestic	priority under 35 U.S.C. §§ 120 and/or 121.			
Attachm		4) [] Indexp. inv. Suprement (DTO 412) Premer No.(1)			
_	otice of References Cited (PTO-892) otice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary (PTO-413) Paper No(s)			
_	formation Disclosure Statement(s) (PTO-1449) Paper No(s).	6) Other:			
**					

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DETAILED ACTION

The amendment filed 7/14/2003 has been entered. Following the entry of the amendment, claims 64-122 are pending.

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 1935 Comm'r Dec. 11 (1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/6/2003 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 64-122 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spinella et al. (5,968,784, issued 10/19/1999).

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Spinella et al. disclose a methods of making one or more cDNA molecules. The method comprises:

- (a) mixing one or more RNA molecules with (I) one or more polypeptides having reverse transcriptase activity and (ii) at least one primer-adapter nucleic acid molecule wherein the at least one primer-adapter nucleic acid molecule comprises one or more ligands and one or more cleavage sites, to form a mixture;
- (b) incubating the mixture under conditions sufficient to make one or more cDNA molecules, wherein one or more of the cDNA molecules comprise at least one primer-adapter nucleic acid molecule;
- (c) contacting one or more of the cDNA molecules with at least one hapten to produce one ore more hapten-cDNA molecule complexes and
- (d) inserting or ligation one ore more of the cDNA molecules into one or more vectors.

 The hapten is avidin or streptavidin (recited in claim 122).

The cleavage site is the site of the restriction enzyme *Not*I producing a *Not*I sticky end.

The vector has a *Not* I compatible end and a blunt end.

The limitations as claimed are disclosed in the teachings of Spinella et al. as set forth below.

The method of Spinella et al. involves preparing double-stranded cDNA from an mRNA using a primer, cleaving the double stranded cDNA with a first restriction site and inserting the cDNA inserts into cloning vector (See column 5, lines 40-55), the primer is immobilized to a

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biotin/avidin beads (See fig. 2) and linked at 5' end of oligo dT sequence to a cleavage site (See column 6, lines 5-11). The restriction site is restriction enzyme, NotI (See column 6, lines 22-23). Spinella et al. also disclose the oligo dT primer is biotinylated and then the biotinylated cDNA is bound to streptavidin beads to remove the rest of sequence (See column 4, lines 7-14) in the method of SAGE.

Spinella et al. do not explicitly disclose that primer-adapter nucleic acid molecule comprises one or more ligands and one or more cleavage sites. However, the primer of Spinella et al. consists of an oligo dT sequence linked at the 5' end of the oligo dT to a cleavage site (See column 6, lines 5-11). It is inherent that the primer of Spinella et al. comprises one or more cleavage sites. The primer of Spinella et al. is immobilized to a biotin/avidin beads (See fig. 2). It is inherent that the primer comprises one ore more ligands. Therefore, the teachings of Spinella et al. anticipate the limitations of claims 64-122.

Alternatively, one of ordinary skill in the art at the time of instant invention would have been motivated to use the method of Spinella et al. to making one or more cDNA molecules.

Although the method of Spinella et al. do not involve forming a hapten-cDNA complex, using hapten as capturing ligand, other capturing ligands was well known in the art to remove the biological material which was not interested in the method, for example, streptavidin beads (See column 4, lines 7-14). In addition, Spinella et al. do not disclose that the vector has a blunt end. However, one of ordinary skill in the art would have been motivated to use the vector which has a blunt end to make one or more cDNA molecule because this was routine practice to choose a

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blunt end vector for optimizing the condition for cloning. Thus, it would have been <u>prima facies</u> obvious to apply the method of Spinella et al. to make one or more cDNA molecules.

Summary

4. No claims are allowable.

5. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

September 17, 2003

ETHAN WHISENANT PRIMARY EXAMINER